REMARKS

Claims 1 and 8 have been amended simply for clarity, to require a step of observing by microscopy and further to require that the method does not include a step of separating the target nucleic acid from non-target nucleic acid. Support for this amendment is found, for example, in the first sentence of paragraph 26. Claim 3 has been amended for clarity to change "different" to "distinguishable." Other amendments are minor modifications, for clarity only. No new matter has been added and entry of the amendment is respectfully requested.

The Invention

The invention as claimed permits identification of a desired region of a target nucleic acid or the presence of a target nucleic acid which does not require the target nucleic acid to be separated from non-target nucleic acids. This is because the sample containing nucleic acids is observed microscopically either on a microscope slide or other surface.

The invention employs oligomers that will bracket a region to be identified as present. By employing two probes, rather than one probe, the sensitivity of the identification can be increased (see paragraph 29). It is necessary only to mix the sample with first and second oligomers that contain particulate labels, and then to observe the proximity of first and second labels using a microscope. No separation steps are required.

The Rejection Under 35 U.S.C. § 112, Paragraph 2

This rejection has been addressed by amendment. Both claim 1 and claim 8 have been amended specifically to specify agreement between the goal of the method in the preamble and the final step. Both claims 1 and 8 have been reworded to clarify the meaning of "nucleic acid" and the

antecedent basis problem has been fixed. Claim 3 has been amended to clarify that the labels are distinguishable from each other. Claims 1 and 8 have been clarified to make specific that "proximity" refers to proximity of the first and second labels to each other. Claim 10 has been amended in response to this rejection to clarify that the fluorophores are the same as each other.

It is believed that the amendments to the claims dispose of the rejections under 35 U.S.C. § 112, paragraph 2. Should additional rewording of claim(s) be required, a telephone call to the undersigned is respectfully requested so that appropriate wording can be worked out by phone.

The Rejection Under 35 U.S.C. § 102

Claims 1-3, 5-6, 8-9 and 12-13 were rejected as assertedly anticipated by Straume, *et al.* (WO 01/027328).

This basis for rejection has been addressed by amendment. Of course, in order for anticipation to occur, each and every limitation of the claim must be disclosed in the Straume document. It is not necessary to include the preamble of the claim in order to find limitations not described in Straume. First, both claims 1 and 8 have been amended to require an active step of observing the proximity of the first and second labels to each other by microscopy. No such observation is disclosed in Straume. Further, both independent claims 1 and 8 now require that the method be conducted without any steps to separate target from non-target nucleic acids. Such steps are an integral part of the procedure described by Straume. As neither of these limitations is included in the Straume disclosure, claims 1 and 8 cannot be anticipated. Similarly, claims dependent thereon cannot be anticipated either. Accordingly, this basis for rejection can be withdrawn.

The Rejection Under 35 U.S.C. § 103

Claims 4, 7, 11 and 14 were rejected as assertedly obvious over Straume in view of Nie (U.S. patent 6,060,242). The secondary document, Nie, is supplied to disclose elements of the rejected claims not specifically taught by Straume. Claim 4 and claim 11 require that the first and second oligomers be peptide nucleic acids; claims 7 and 14 require a multiplicity of target nucleic acids. However, Straume fails to defeat patentability of the independent claims on which these claims depend. For this reason alone, the combination cannot defeat patentability of claims 4, 7, 11 or 14.

Claim 16 was rejected over the combination of Straume in view of Ward (U.S. patent 6,506,563). The secondary reference, again, is cited to disclose the limitation of claim 16 wherein the organism from which the nucleic acid is derived is an infectious agent. As above, because Straume does not suggest the invention of the independent claims, the disclosure of the dependent claim feature by the secondary reference does not defeat patentability.

Claim 17

It is noted that there is no outstanding rejection of claim 17 over the art.

Conclusion

The claims have been amended in response to the rejection under 35 U.S.C. § 112, paragraph 2, for clarification. It is believed that the claims as amended are clear of this rejection.

Independent claims 1 and 8 have been amended to distinguish them clearly from the primary reference, Straume. Two additional limitations have been included – a step of observing the sample by microscopy and the requirement that no steps to separate target from non-target nucleic acids be

included in the method. Accordingly, the rejections of claims 1-16 over the art may also be withdrawn. There is no outstanding art rejection of claim 17.

Applicants thus believe that claims 1-17 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 388512011000.

Respectfully submitted,

Dated: November 14, 2006 By: Kate H Murashige

Kate H. Murashige
Registration No. 29,959
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
Telephone: (858) 720-5112
Facsimile: (858) 720-5125